

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



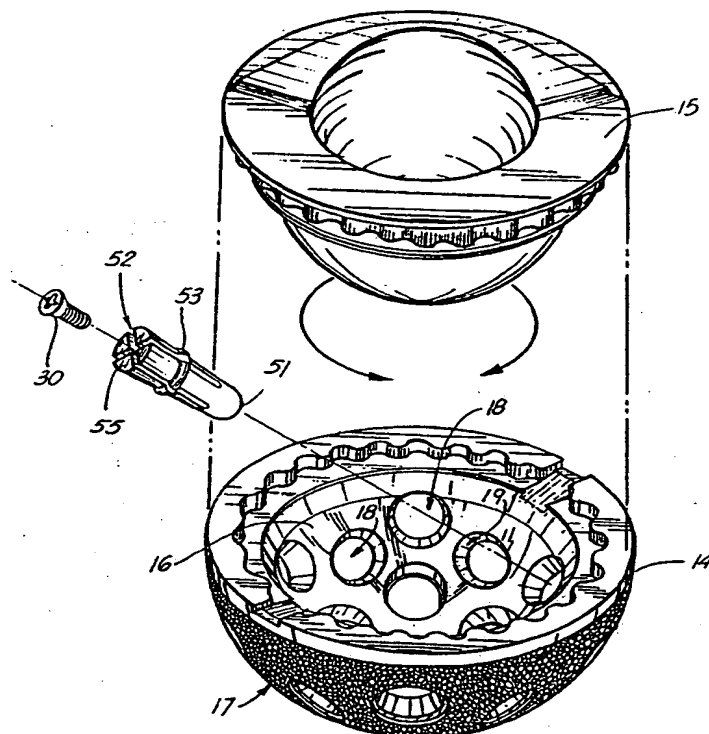
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>5</sup> : <b>A61F 2/32</b>		<b>A1</b>	(11) International Publication Number: <b>WO 94/05234</b>
			(43) International Publication Date: 17 March 1994 (17.03.94)
(21) International Application Number: <b>PCT/US93/08295</b>		(74) Agent: KRIEGER, Paul, E.; Pravel, Hewitt, Kimball & Krieger, Tenth Floor, 1177 West Loop South, Houston, TX 77027 (US).	
(22) International Filing Date: 31 August 1993 (31.08.93)			
(30) Priority data: 07 938,421 31 August 1992 (31.08.92) US		(81) Designated States: AU, CA, JP, UZ, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(71) Applicant: SMITH & NEPHEW RICHARDS INC. [US/US]; 1450 Brooks Road, Memphis, TN 38116 (US).		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(72) Inventors: SCHRYVER, Jeff ; 28 Summer Grove Road, Cordova, TN 38018 (US). SHEA, Jeff ; 623 South Yates, Memphis, TN 38120 (US). RYAN, Dawn, Michelle ; 4138 Garden Birch Cove, Memphis, TN 38120 (US).			

(54) Title: ACETABULAR CUP BODY PROSTHESIS

(57) Abstract

An improved acetabular cup prosthesis (10) has a cup body (17) with correspondingly shaped inner convex and outer concave surfaces. A polymer liner (15) fits and attaches to the cup (10) at the concave surface. The inner convex surface is highly polished and mirror-like for retarding debris generation with the polymer liner and allowing optical pattern inspection. A plurality of bores (18) can be provided, extending between an inner concave surface and an outer convex surface, wherein the bores (18) can function as drill guides for providing alignment in the drilling of surgical openings after the acetabular cup body (10) is placed in a patient. A plurality of pegs or spikes (52) have proximate end portions (55) that have connection members for forming connections with the bores, and distal end portions (51) that can register into the drilled surgical openings.



BEST AVAILABLE COPY

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NE	Niger
BE	Belgium	GN	Guinea	NL	Netherlands
BF	Burkina Faso	GR	Greece	NO	Norway
BG	Bulgaria	HU	Hungary	NZ	New Zealand
BJ	Benin	IE	Ireland	PL	Poland
BR	Brazil	IT	Italy	PT	Portugal
BY	Belarus	JP	Japan	RO	Romania
CA	Canada	KP	Democratic People's Republic of Korea	RU	Russian Federation
CF	Central African Republic	KR	Republic of Korea	SD	Sudan
CG	Congo	KZ	Kazakhstan	SE	Sweden
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovak Republic
CM	Cameroon	LU	Luxembourg	SN	Senegal
CN	China	LV	Latvia	TD	Chad
CS	Czechoslovakia	MC	Monaco	TG	Togo
CZ	Czech Republic	MG	Madagascar	UA	Ukraine
DE	Germany	ML	Mali	US	United States of America
DK	Denmark	MN	Mongolia	UZ	Uzbekistan
ES	Spain			VN	Viet Nam
FI	Finland				

**ACETABULAR CUP BODY PROSTHESIS**

5        This is a continuation-in-part application of co-  
pending U.S. Patent Application Serial No. 07/938,421,  
filed August 31, 1992, which is a continuation-in-part  
application of U.S. Patent Application Serial No.  
07/830,243, filed February 10, 1992, which is a  
10 continuation-in-part of U.S. Patent Application Serial No.  
07/656,247, filed 02/14/91, now U.S. Patent No. 5,226,917,  
all incorporated herein by reference.

**SPECIFICATION:****BACKGROUND OF THE INVENTION:**

15        **1. Field Of The Invention:**

The present invention relates to acetabular prosthetic  
devices and more particularly to an improved acetabular  
prosthesis (and method of surgically implanting), wherein  
the prosthesis has a cup or shell with an inner concave  
20 surface that has a mirror-like polished surface. The shiny  
polished inner, concave surface faces a cup liner (eg.  
polymeric) so that relative motion between the liner and  
shell will generate minimal liner debris. The polished  
shell concave surface has a roughness of preferably less  
25 than eight (8) micro inches. The body or shell can include  
radially extending bores therethrough that can be used as  
drill guides by a surgeon after the acetabular cup or shell  
has been placed in the patient's acetabulum. Holes can be  
drilled surgically into the underlying bone tissue using  
30 the drill guide openings so that one or more pegs for  
improved anchoring can be placed into the bores and affixed  
rigidly to the acetabular cup using an interference or  
wedge fit. The prosthesis (including cup or shell and  
rigidly affixed pegs) is thus anchored into the underlying  
35 surgical openings.

**2. General Background:**

There are a number of commercially available

-2-

acetabular prosthetic devices that include a cup shaped body. Some of these acetabular cups have correspondingly shaped inner and outer concave and convex surfaces. Some devices have projections extending from the outer surface  
5 of the cup-shaped body. For example, U.S. Patent No. 3,939,497 describes a socket for a hip joint prosthesis which is secured to a cavity in the bone tissue by a series of radially arranged pegs which can be projected outwardly from the wall of the socket into the surrounding tissue by  
10 a central screw which also has a self-tapping thread that enters the tissue.

U.S. Patent No. 4,685,923 provides a hip joint socket made from a plastics material that can be installed without the use of bone cement or adhesive. The socket comprises  
15 a hemisphere of polyethylene. The socket may have four bores extending skewed to the equatorial plane to permit the surgeon to fix the socket in the acetabulum by means of screws or dowels temporarily or permanently. The primary anchoring is provided by two plugs or pins arranged on the  
20 outer surface of a socket. The pins may be substantially parallel to each other. The pins are inserted in bore holes drilled into the bone. The bore holes are drilled so that the pins are inserted under stress. A secondary anchor in the form of flaps are present near the actuarial  
25 plane of the socket. These flaps supplement the anchoring affect of the pins.

In U.S. Patent No. 4,792,337 an acetabular cup is provided which has a metallic anchoring shell. The cup is for cement-less fixation in the acetabulum. The shell has  
30 several holes through which screws are driven into the bone. The screws have rounded heads and the holes are countersunk so that the orientation of the screws may be varied with respect to the cup and each other.

In U.S. Patent No. 4,828,565 there is provided a  
35 cotyliodal component for a non-cemented hip prosthesis. The component has two parts, a titanium hemispherical shell and a cup of polymer which is engaged into it. The shell

-3-

has two zones, the first zone is covered with porous titanium capable of being invaded by spongy bone and also has two projecting pieces. The other zone has a smooth metal surface. Two screws pass through the projecting  
5 pieces and are used to anchor the component in the acetabulum.

Another acetabular cup for cement-less fixation in the acetabulum is described in European Patent Application No. 13,863, published June 8, 1980. The cup is anchored to the  
10 bone by a central pin and a number of other pins distributed over the surface of the cup. The pins have several sawtooth notches along their length. The bone may be pre-drilled to take the pins.

European Patent Application No. 169,978 published May  
15 2, 1986, describes an acetabular cup which has an outer shell embedded into the patient's pelvis. The outer shell has a frustro-conical skirt and a spherical central cap. The shell has a number of small tufts with rounded ends projecting from its surface. The tufts are embedded in the  
20 bone tissue to provide improved anchorage.

In European Patent Application No. 211,169 published February 25, 1987, an acetabular cup is described in which an external boss protrudes from the outer surface of the acetabulum body to fit into a pre-drilled hole in the  
25 acetabulum. The cup also has two anchoring lugs in the meridian plane. The lugs take screws to aid in anchoring the cup.

Other foreign patents and patent applications which describe acetabular cups include European Patent  
30 Application No. 212,087 published April 3, 1987, wherein metallic pins project from the surface of the cup and contain holes in which tissue may grow. In European Patent No. 341,198 published November 8, 1989, an acetabular cup has a metal outer shell and a plastic body for retaining  
35 the hip joint head. The shell is frustro-conical in cross-section with an opening at an apex and circular teeth around the outside. Three or more anchoring dowels

-4-

parallel to the convexes protrude from the outer surface of the shells. The dowels are slotted and provide with circular teeth of a sawtooth cross-section over the portions which protrude. A central bolt may be fitted into  
5 the dowel to provide a rounded end.

The use of cement for fixation of acetabular process, and in some cases the use of spacers, is found in U.S. Patent Nos. 4,563,778, and 4,566,138. This concept of the use of bone cement and spacers is also seen in United  
10 Kingdom Patent Nos. 1,170,295 and 2,080,118.

U.S. Patent No. 4,923,473, issued to Peter Griss et al., entitled "Hemispherical Acetabulum", relates to a hemispherical acetabulum having a fixing pin which projects from the outside surface of the acetabulum.

15 In prior art acetabular cup prosthetic devices, the projections or spacers are often for the sole purpose of providing a space from the bone tissue that can be occupied by bone cement. Further, many acetabular cup prosthetic devices carry projections on their outer surface which are  
20 a part of the prosthesis as constructed and which cannot be added thereafter such as during surgery.

Still other prosthetic devices in the form of acetabular cups provide pegs which must be affixed to the tissue before the acetabular cup is placed in the position.  
25 Pegs which are preattached to the cup may require predrilling or other preparation which includes impaction for the purpose of forcing the projections into the bone. The bone bed may require advance preparation in some devices to accept the protrusions.

30 **SUMMARY OF THE PRESENT INVENTION:**

The present invention provides an improved acetabular cup prosthesis wherein the prosthesis body has an inner concave surface and an outer convex surface and an annular base that defines a base claim.

35 A polymeric cup liner registers and affixes to the cup body at the concave surface portion.

The cup body concave surface has a polished mirror-

-5-

like surface that faces the liner for retarding liner debris generation. The polished surface has a roughness of preferably less than eight (8) micro inches. This surface finish in its interior spherically shaped dome or concave  
5 portion is the contact interface between the metallic shell and the acetabular polyethylene or polymer liner. The surface finish has numerous advantages.

First, it provides a low friction and low abrasion surface for distributing the contact forces between the  
10 polyethylene liner (UHMWPE) and the shell. This reduces the abrasive generation of polyethylene debris resulting from motion between the liner and shell.

This motion may come from a variety of mechanisms which include Poisson volumetric distortion of the  
15 polyethylene resulting in localized expansion and contraction of the surface of the liner against the shell as a result of loading of the femoral head in the liner, and the micro-motion which occurs from forces from the femoral head pushing the liner within and around the  
20 confines of the shell interior.

The mirror finish allows the use of optical non-contact inspection of the interior of the shell surface for checking the geometric correctness of the shell. The use of non-contact optical inspection methods allow complete  
25 checking of whole two and three dimensional surfaces at one time. The usual method of optical three-dimensional inspection is to project a regular pattern of light onto the surface which is to be inspected. The resultant two dimensional projection of the scene may be used to give  
30 highly accurate total surface measurement. Distortions in the regular pattern indicate distortions in the part surface and indicate deviations from the desired part geometry. This method is ineffective on highly smooth surfaces since the projected light of the regular pattern  
35 bounces off the measurement target and no two dimensional mapping is possible. In this device idea the highly smooth surface (which is smooth due to the requirements of

-6-

paragraph 1 above) is further polished to act as a reflective mirror. This surface mirror then is used as a lens to view a two-dimensional pattern such as a grid drawn on a white sheet of paper or a series of concentric rings.

5 Distortions in the viewed image then are a result of distortions of the lens and hence the surface which is desired to be measured. It is thereby possible to inspect the highly smooth surface of the acetabular device due to this polishing.

10 The method of inspection may be both by trained human inspectors and by image analysis performed by capturing the reflected image by a video camera, digitizing the image, and using computer analysis to measure the amount of deviation of the pattern from the allowed surface geometry  
15 tolerance.

The advantages of this smooth and polished surface is therefore to provide non-contact, and therefore non-destructive (non-scratching), measurement of the interior of an acetabular device. The inspection methods require a  
20 surface which allows a reflective resolution sufficient to provide adequate reflective image quality for analysis. Our current inspection limits require a surface finish of less than eight (8) micro-inches to accomplish this quality of resolution.

25 The cup body preferably includes openings therethrough which can function as drill guides for the surgeon after the cup has been placed in the patient's acetabulum. The present invention affords improved fixation and stability of the component because pegs can be placed in the  
30 acetabular cup after it has been placed in position by the surgeon. The pegs can be easily installed from the concave side of the acetabular cup component notwithstanding the fact that the acetabular cup component has already been placed in operative position in the patient's acetabulum.

35 With the present invention, a multiplicity of pegs can be rigidly attached to the acetabular cup prosthesis body for the purpose of securing it in place in the acetabular



-7-

bone. This can be done through an opening or bore which is interchangeably used for a desired peg.

With the present invention, the acetabular cup can be placed in it's desired position in the acetabulum by the surgeon. The pegs (as described more fully herein) are then added to the cup body and attached to the prosthesis in a rigid fashion. Each peg protrudes through the acetabular cup body and into the underlying bone tissue of the acetabulum to provide a mechanical locking of the acetabular cup (including pegs) into the pelvis. The surgeon can use a pre-drill before placing the peg or spike wherein the opening or bore in the acetabular cup body functions as a drill guide. Pegs can be selectively placed so that they are not aligned with each other but are at angles to each other which aids in the mechanical stability of the acetabular cup body.

The apparatus preferably uses a plurality of pegs that feature a taper or wedge lock, barb lock, or knurl lock, to form an interference fit, or compression friction lock, and a rigid connection with the acetabular cup at the drill guide openings. The interference fit assures a rigid connection between peg and cup body so that each peg and cup body move together, rather than relative to one another. Relative motion causes possible contact between a peg and any polymer liner, creating the problem of liner debris generation. The pegs are smooth along the distal portion thereof so that movement of the peg and cup as a unit will not disrupt adjacent bone tissue.

The present invention thus provides an improved acetabular cup prosthesis that includes an acetabular cup body or shell component, having an inner concave surface and an outer convex surface.

A plurality of openings extend between the inner and outer surfaces along radial lines that can merge substantially near a center of curvature of the inner concave surface of the cup body, the openings forming elongated bores surrounded by a bore wall portion of the

-8-

acetabular cup body. The cup body or shell can be spherical in form, or not spherical in form (such as e.g., an egg-shaped cup or shell).

5 The plurality of openings are positioned to define drill guides so that during a surgical implantation of the prosthesis, the surgeon can selectively drill into the underlying tissue through one or more of the openings and form surgical openings therein in the underlying bone tissue.

10 There are preferably a plurality of peg members, each being insertable into and registering with one or more of the openings in the prosthesis body, the peg members having a first proximate end portion having means thereon for forming a rigid connection with the acetabular cup body at one of the openings and with the bore wall, and a second smooth distal end portion adapted to extend into the underlying tissue (e.g., into surgically formed openings) after the cup body has been implanted in a patient.

BRIEF DESCRIPTION OF THE DRAWINGS:

20 For a further understanding of the nature and objects of the present invention, reference should be had to the following detailed description taken in conjunction with the accompanying drawings, in which like parts are given like reference numerals, and wherein:

25 FIGURE 1 is a side sectional view of a first embodiment of the apparatus of the present invention;

FIGURE 2 is a perspective view of the first embodiment of the apparatus of the present invention;

30 FIGURE 3 is an exploded perspective view of the first embodiment of the apparatus of the present invention;

FIGURE 4 - 4A are fragmentary views of the first embodiment of the apparatus of the present invention;

35 FIGURES 5A - 5C are bottom, side, and top views of peg portion of the first embodiment of the apparatus of the present invention;

FIGURES 6A - 6C are bottom, side, and top views of another peg as used with the first embodiment of the

-9-

apparatus of the present invention;

FIGURES 7A - 7C are bottom, side, and top views of a spike member as used with the first embodiment of the apparatus of the present invention;

5        FIGURES 8, 9, 10, and 11 are peg members used with the first embodiment of the apparatus of the present invention including respectively thread lock, barb lock, taper lock, and knurl lock embodiments thereof;

10       FIGURES 12A - 12D are top views of locking pin members used with the taper locking embodiment of the spike;

FIGURE 13 is a perspective fragmentary view of the first embodiment of the apparatus of the present invention illustrating the peg locking screw portion thereof;

15       FIGURE 14 is a perspective fragmentary view illustrating an interface of the peg locking screw with one of the pegs of FIGURES 5A - 5C;

FIGURE 15 is a partial sectional view illustrating the peg of FIGURE 10;

20       FIGURE 16 is a perspective view of a second and preferred embodiment of the apparatus of the present invention;

FIGURE 17 is a fragmentary view illustrating a peg member used with the second embodiment of the apparatus of the present invention;

25       FIGURE 18 is a fragmentary view illustrating the closure member portion of the second embodiment of the apparatus of the present invention; and

30       FIGURE 19 is a fragmentary sectional view illustrating the second embodiment of the apparatus of the present invention;

FIGURE 20 is a another fragmentary sectional view illustrating the second embodiment of the apparatus of the present invention;

35       FIGURE 21 is a another fragmentary sectional view illustrating the cup portion of the second embodiment of the apparatus of the present invention;

FIGURE 22 is a fragmentary sectional view of the

-10-

second embodiment of the apparatus of the present invention illustrating the cup and cup liner connection;

FIGURE 23 is a schematic diagram of the grid used to inspect the polished surface for distortions;

5       FIGURE 24 is a second embodiment of a test grid pattern used to inspect the highly polished surface portion of the acetabular cup prosthesis of the present invention;

FIGURE 25 is a schematic diagram of a test grid showing no surface defects; and

10       FIGURE 26 is schematic diagram showing local defects for a polished surface that has been inspected using the grid.

**DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT:**

In Figure 1 there can be seen a sectional view of the first embodiment of the apparatus of the present invention designated generally by the numeral 10. In FIGURE 1, there can be seen a hip prosthesis member 11 mounted in a femur 12 of a patient. The hip prosthesis 11 includes an upper ball portion 13 that registers with the acetabular prosthetic apparatus 10 of the present invention.

20       The acetabular prosthesis 10 includes a cup or shell prosthesis body 14, preferably of a metallic material with a plastic liner 15 portion. The metallic cup body 14 includes an inner concave surface 16 and an outer convex surface 17. The surfaces 16, 17 are spaced apart, defining the thickness of the cup or shell 14. The cup body 14 provides a three-dimensional surface that is sintered to the outside surface 17 (such as sintered beads). The inside 17 is then machined after sintering. Another type of roughened outer surface 17 could be provided such as plasma sprayed metal, plasma sprayed hydroxyl apatite, or a mechanically textured or roughened surface. The shell or cup body 14 could have an exterior surface optimized for use with bone cement.

35       A plurality of openings 18 in form of preferably elongated bores extend between the inner concave surface 16 and the outer convex surface 17. These openings are in the

-11-

form of bores having a bore wall 19 as seen in Figure 3. The openings 18 can function as drill guides for the surgeon. Therefore, once the metallic cup body 14 portion of the acetabular cup prosthesis 10 is placed in position in the patient's acetabulum as shown in Figure 1, the surgeon can simply drill through any one of the plurality of bores forming an opening in the underlying bone tissue designated generally be the numeral 20.

When the surgeon places the cup body 14 in the position shown in Figure 1, the plurality of bores 18 can act as a drill guide for the surgeon. The bore 19 walls of each opening 18 define a cylindrically shaped guide for a correspondingly sized drill. These openings allow the surgeon to form surgical openings in the underlying bone tissue 20.

A selected surgically formed opening 18 is then occupied by a peg (and not necessarily each opening 18), such as one of the pegs 25 - 29, as seen in Figures 1 - 3 and 4A. In the preferred embodiment, each of the pegs 25 - 29 extends into the bone tissue at a different angular position with respect to the other pegs to provide a rigid anchor for the cup 14. Pegs 25-29 can be polymer, metal, or resorbable polymer.

Once the pegs 25 - 28 are placed into operative position, a strong connection is formed between the outer surface of each peg 25 - 28 and the walls 19 of each opening or bore 18. In Figures 5A - 5C, 6A - 6C, 7A - 7C, and 8 - 11, various embodiments of the pegs, their respective attachments to the cup body 14 are illustrated.

In Figure 8, peg 25A includes a proximate end portion 31 and a distal end portion 38A and a central longitudinal axis 34. A smaller diameter section 33 connects with a larger diameter section 32 that is covered with an external spiralling thread 39. The thread 39 bites into and interfaces with the cup body 14 at the wall 19 of each opening 18. The opening or bore 18 wall 19 can also be internally threaded to engage the thread 39.

-12-

In Figure 9, peg 25B is provided with a proximate end 31, a distal end 38, a smaller diameter section 33, and a larger diameter section 32 that carries a plurality of annular barb rings 40. When the peg 25B is forced into the opening 18, the barbs 40 form a tight fit with the cup body 14 at the wall 19 of each opening 18.

In the embodiment of Figures 10, 11, and 15, pegs 25C, 25D provide a proximate, larger diameter 41 end portion, a smaller generally cylindrical distal end portion 44, and a transitional frustro-conical section 42, and a curved end 43. Similarly, peg 25D has a proximate, larger diameter 45 portion, a curved annular transition section 46, a smaller and generally cylindrical section 47, and a curved end portion 48. The large diameter section 41 and the frustro-conical portion 42 can also be seen in Figure 15 in a partial sectional view. The larger diameter and frustro-conical sections 41, 42 surround an internally threaded bore 68 which accepts set screw 30. The screw 30 is sized to expand the enlarged 41 and frustro-conical 42 sections slightly when the peg 25C is placed in position within one of the bores 18 which would be similar in shape to the outside surface of frustro-conical portion 42 and enlarged portion 41.

When the set screw 30 is fully threaded into the threaded opening 68, so that the external thread 67 of the set screw 30 engages the internal thread 68 of the bore, a taper lock connection or interference fit is formed between the peg 25C and the wall 19 of opening 18. Internal threads 68 in Figure 15 can also be used as an extraction or holding means for placing and removing the peg 25c. Peg 25c would be used then without a screw 30.

The set screw 30 can have different tooled sockets, as shown in Figures 12A - 12D. In Figure 12A, a set screw 30A includes a square tooled socket 63. In Figure 12B, the set screw 30B has a X-shaped slot 64 for receiving a Phillips-type screwdriver, for example. In Figure 12C, the set screw 30C has a single transverse slot 65 and in the

-13-

embodiment of Figure 12B, the set screw 30B has an hexagonal tool socket 66. Other tooled sockets could be employed.

5 In Figures 4 - 4A, the pegs 25C can be shown extending from the convex 17 surface of cup body 14 and into a surgically formed opening 70 which is formed by the drill that penetrates the opening 18. In such a situation, the surgeon simply uses the opening 18 as a drill guide for a similarly shaped drill when forming surgical opening 70.

10 In Figures 5A - 5C, an alternate construction of the peg is illustrated, designated generally by the numeral 50A. Peg 50A includes a rounded or hemispherical distal end portion 51 and a proximate end portion 52 that includes a pair of longitudinally extending slots 49, forming four  
15 peg sections 55.

In the embodiments of Figures 6A - 6C, the peg 50B provides a hemispherical distal tip 51 and a single longitudinally extending transverse slot 49 forming two peg sections 55. Enlarged annular shoulder 53 and smaller  
20 diameter recess 54 are also provided in each of the embodiments of Figures 5A-5C and 6A - 6C.

In the embodiment of Figures 7A - 7C, a spike-shaped peg 56 is provided having a pointed tip portion 57, and a plurality of beveled surfaces 58 that connect with a  
25 cylindrical peg body portion that includes an enlarged annular section 60 and a smaller diameter constricted section 59. The proximate 61 end portion of the peg includes a longitudinally extending Y-shaped slot 62, as seen in Figures 7B and 7C.

30 Figures 16-22 illustrate a second and preferred embodiment of the apparatus of the present invention designated generally by the numeral 70. Acetabular cup apparatus 70 includes a cup body 71 to which can be removably affixed a plastic cup liner 72 made of  
35 polyethylene for example. Liner 72 has an inner concave surface 73 and an external convex surface 74. Liner 72 is in the form of a hemispherical member having an annular

-14-

base 75 with a plurality of curved members extending around the periphery of liner 72 at base 75 and which interface with a similarly shaped circumferentially recess formed on cup body 71 to prevent rotation of liner 72 with respect to  
5 body 71. The cup body 71 is preferably metallic having an annular base 76 that defines a plane. The cup body 71 has an inner concave surface 77 and an external convex surface 78. The cup body 71 concave surface 77 is a shiny polished surface that faces the convex surface 74 of polymeric liner  
10 72. The polished concave surface 77 has a roughness of less than sixteen (16) micro-inches, and preferably about eight (8) micro-inches. Such a highly polished surface 77 appears mirror-like. The polished concave surface 77 inhibits polymer liner debris generation.

15 External surface 78 can be covered with a plurality of small metallic beads or the like forming a bone ingrowth surface 79. The apex 80 of cup body 71 has a through opening 81 that has an internal thread 82 for attachment thereto of a tool for inserting and/or removing the cup  
20 body 71 from its position in the acetabular bone tissue of a patient.

A plurality of four openings 84, 85, 86 and 87 are provided preferably in one quadrant 88 of cup body 71. Each opening 84-87 has an internal opening configuration  
25 that includes a larger diameter generally cylindrically shaped opening portion 91 and a smaller diameter opening portion 92 (Figure 20). The larger and smaller diameter sections 91, 92 are interfaced by an annular shoulder 93. The smaller diameter section 92 can be tapered from a point  
30 of maximum diameter adjacent annular shoulder 93 to a point of minimal diameter adjacent the annular shoulder 89. A second larger diameter cylindrical section 90 meets outer edge 94 of each opening 84-87.

Pegs 95 can be selectively fitted into any one of the  
35 openings 84-87 during use. Each peg 95 has a tapered section 96 that includes a larger diameter circular base 97 defining a proximate end portion of peg 95. Distal end



-15-

portion 98 of peg 95 is generally cylindrical and smooth, and includes a curved or hemispherical smooth tip 99.

In Figure 20 force arrows are used to demonstrate that the above-described connection between each peg 95 and the cup body 71 is a substantially rigid connection that produces load transfer between each peg member and the cup body of tension loads, compression loads, axial torsion loads, and bending moment loading. Thus, the peg 95 does not rotate nor back out with respect to the opening 85-87.

10

The force arrow 117 is an angled force having both a bending force component ( $F_b$ ) designated as 118 and a compression force component ( $F_c$ ) designated as 119. The force arrows 120 and 124 show shear forces at the interface between peg 95 and cup body 71 at a selected opening 84 - 87. The force arrows 121A,B are force arrows that are resisting the shear forces and the force arrows 122A,B are resisting bending forces.

A closure member 100 is shown in Figures 18-19 and includes a larger section 101 and a smaller diameter section 102. Annular shoulder 103 forms an interface between the larger 101 and smaller 102 diameter sections. Closure member 101 has an enlarged circular base 104 defining its proximate end portion during use and a smaller circular flat distal end 105.

The larger diameter section 101 of closure member 100 can have a beveled annular wall 106 for forming a wedge type fit with the larger diameter section 91 of a particular selected opening 84-87. In this manner, the closure member 100 can be placed in any one of the selected openings 84-87 and pressed into the selected opening 84-87 by the user even after the cup body 71 has been placed into operative position. The user simply presses the closure member 100 into one of the selected openings 84-87 by accessing the cup body 71 from the concave 77 side.

The surgeon can close any one of the selected openings 84-87 using the closure member 100 after the cup body 71

-16-

has been placed in the desired operative position and anchored into position using one or more of the pegs 95. The closure member 100 may be placed in the shell 71 before implantation, such as during manufacturing, and then  
5 selectively removed by the surgeon before use of the shell 71. Each closure member 100 occupies a position in its selected opening 84-87 and between the convex 78 and concave 77 surfaces of shell or cup body 71.

Each of the openings 84-87 has a generally cylindrical  
10 smaller diameter section 92 that can act as a drill guide for the surgeon so that drilled openings can be made into the underlying bone tissue after the acetabular cup body 71 has been placed into position. This allows one or more  
15 pegs to be placed into one or more of the selected openings 84-87. Any of the selected openings 84-87 that are not selected can be plugged using the closure member 100. This prevents the flow of the polyethylene liner into any of the openings 84-87 that are not occupied by a peg 95. The  
20 closure member 100 friction fits into the above-mentioned larger diameter portion 91 of the openings 84-87.

In Figure 22, the connection between cup 71 and liner 72 is illustrated with greater detail. Liner 72 can be rotated as shown by arrows 107 in Figure 16 until the raised portion 75A of base 75 is in a selected position.  
25 The liner 70 is then fitted to the cup 71 by engaging the annular recess 116 of the cup 71 with the annular corrugated shoulder 108 of the liner 72. Shoulder 108 has an inclined annular shoulder that forms an acute angle of between about eighty and eighty five degrees with the flat  
30 upper surface 111 of annular base 75 of liner 72.

The surface 111 is flat so as to register with the surface of base 76 of cup 71. The numeral 112 in Figure 22 designates the angle between surface 111 and inclined annular wall 109. A recess 116 has a corresponding shape  
35 and size to the annular corrugated shoulder 108. The angle 113 formed between inner inclined annular surface 114 and annular surface 115 is the same angular measure as angle

-17-

112.

This configuration of annular shoulder 108 and recess 116 provides a snap or interference fit between the liner shoulder 108 and the cup 71 at recess 116 which helps  
5 secure the liner 72 to the cup 71 during use.

Figures 23-26 illustrate grid charts 200, 205 that can be drawn on a white sheet of paper for example and used to inspect the highly polished inner concave surface 16 of acetabular cup body 14 for defects. In Figure 23, a grid  
10 200 is in the form of a plurality of concentric rings 201, 202, 203, etc. A central opening 204 allows the user to visually inspect the inside surface 16 of the cup body 14 when the flat grid 200 is placed on top of the cup body 14 with the print of chart 200 facing the mirror like polished  
15 concave surface 16. In this fashion, the user simply views the lined pattern of the concentric rings 201-203 of grid chart 200 as reflected off the mirror surface of the inside, concave surface 16 of the cup body 14.

In Figure 24, a generally rectangularly shaped test  
20 grid 205 is shown. In Figure 25, a reflective pattern for the test grid 205 is shown as pattern 206, showing no defects. In Figure 26, another test grid pattern reflection 207 is shown that notes two local defects 208, 209.

25 Figure 23 illustrates a method of inspection that may be by trained human inspectors, simply looking through the central opening 204. When such human inspection is employed, the inspector simply looks through the opening 204 when the grid chart 200, 205 is placed against the  
30 concave 16 side of acetabular cup body 14.

Another method of inspection may be by image analysis performed by capturing the reflected image with a video camera, digitizing the image and using computer analysis to measure the amount of deviation of the pattern from the  
35 allowed surface geometry tolerance. Thus, the surface 16 defines a mirror that is used as a lens to view a two dimensional pattern such as the grid patterns 200, 205

-18-

drawn for example on a white sheet of paper. Distortions in the viewed image are then a result of distortions of the lens surface 16 and hence the surface which is desired to be measured.

- 5 The following Table 1 lists part numbers and corresponding part descriptions as used herein and in the drawings:

TABLE 1 - PARTS LIST

	<u>PART NUMBER</u>	<u>PART DESCRIPTION</u>
10	10	acetabular cup apparatus
	11	hip prosthesis member
	12	femur
	13	ball portion
	14	cup body
15	15	plastic liner
	16	inner concave surface
	17	outer convex surface
	18	openings
	19	bore wall
20	20	bone tissue
	25-29	pegs
	25A-D	pegs
	30	set screw
	31	proximate end
25	32	larger diameter section
	33	smaller diameter section
	34	longitudinal axis
	38	distal end of peg 25B
	38A	distal end of peg 25A
30	39	thread
	40	annular barb rings
	41	larger diameter end
	42	frustro-conical section
	43	curved end
35	44	distal end portion
	45	larger diameter end
	46	transition section

-19-

	47	smaller diameter section
	48	curved portion
	49	slot
	50A	peg
5	51	hemispherical end
	52	proximate end
	53	annular shoulder
	54	annular recess
	55	peg sections
10	56	peg
	57	pointed tip
	58	beveled surface
	59	smaller diameter section
	60	annular shoulder
15	61	proximate end
	62	slot
	70	acetabular cup apparatus
	71	cup body
	72	cup liner
20	73	concave surface
	74	convex surface
	75	annular base
	75A	raised portion
	76	annular base
25	77	concave surface
	78	convex surface
	79	bone ingrowth surface
	80	apex
	81	opening
30	82	threaded portion
	84	opening
	85	opening
	86	opening
	87	opening
35	88	quadrant
	89	shoulder
	90	larger diameter cylindrical section

-20-

	91	larger diameter cylindrical section
	92	smaller diameter section
	93	annular shoulder
	94	annular edge
5	95	peg
	96	tapered section
	97	base
	98	distal end of peg
	99	hemispherical tip
10	100	closure member
	101	larger diameter section
	102	smaller diameter section
	103	annular shoulder
	104	larger base
15	105	distal end of closure member
	106	beveled annular wall
	107	curved arrow
	108	annular corrugated shoulder
	109	angled annular sidewall
20	110	upper flat surface
	111	upper surface of annular base
	112	angle
	113	angle
	114	inner inclined annular
25		surface
	115	annular surface
	116	annular recess
	117	force arrow
	118	force component, bending
30	119	force component, compression
	120	force arrow, shear
	121A,B	force arrows
	122A,B	force arrows
	123	force arrows
35	124	force arrow, shear
	125	force arrows, torsion
	200	circular grid pattern chart

-21-

	201	concentric ring
	202	concentric ring
	203	concentric ring
	204	central opening
5	205	rectangular grid pattern chart
	206	reflective pattern - test grid
10	207	reflective pattern - test grid
	208	defect
	209	defect

Because many varying and different embodiments may be made within the scope of the inventive concept  
15 herein taught, and because many modifications may be made in the embodiments herein detailed in accordance with the descriptive requirement of the law, it is to be understood that the details herein are to be interpreted as illustrative and not in a limiting  
20 sense.

What is claimed as invention is:

**CLAIMS:**

1. An acetabular cup prosthesis, comprising:
  - a) an acetabular cup body having an inner concave surface, an outer convex surface, and an annular base that defines a base plane;
  - b) a polymeric cup liner that registers with and affixes to the cup body at the cup body concave surface;
  - c) wherein the cup body concave surface has polished inner surface means that faces the liner for retarding liner debris generation, and including a polished surface having a roughness of less than eight (8) micro-inches.
2. The acetabular cup prosthesis of Claim 1 further comprising an array of openings over the cup body and a plurality of peg members removably connectable with the cup body at the openings.
3. The acetabular cup prosthesis of Claim 2 wherein each of the openings defines a smooth walled bore.
4. The method of Claim 3 wherein the bore defines a drill guide.
5. The apparatus of Claim 1, wherein the shell has inner and outer concave and convex surfaces that are of corresponding curvature.
6. The apparatus of Claim 1, wherein each of the openings has a generally cylindrically shaped bore portion.
7. The apparatus of Claim 1, wherein the elongated bores include a generally cylindrical portion and a generally frustro-conical portion.
8. The apparatus of Claim 2, wherein the plurality of peg members are each generally cylindrically shaped in configuration.
9. The apparatus of Claim 2, wherein the plurality of peg members include a proximal section of larger diameter and a distal section of smaller



-23-

diameter.

10. The apparatus of Claim 1, wherein the acetabular cup body is of a metallic material at the bores.

5 11. An acetabular cup prosthesis, comprising:

a) an acetabular cup body having an inner concave surface and an outer convex surface;

b) a plurality of openings that extend between the inner and outer surfaces along lines that  
10 converge substantially near the center of curvature of the inner concave surface, the openings forming elongated bores surrounded by a bore wall portion of the acetabular cup body;

c) one or more peg members, each being  
15 insertable into and registering respectively with one of the openings, each peg member having a first proximate end portion having means thereon for forming a substantially rigid connection with the acetabular cup body at one of the openings and with the bore wall that enables load transfer between the cup body and  
20 peg members without substantial rotational or translational movement between the cup body and each peg member, and a second distal end portion adapted to extend into the underlying tissue after the cup body  
25 has been implanted in a patient; and

d) wherein the cup body concave surface has polished inner surface means that faces the liner for retarding liner debris generation, and including a polished mirror surface.

30 12. The acetabular cup prosthesis of Claim 11 wherein the polished inner surface means is a mirror-like surface having a roughness of less than eight (8) micro inches.

35 13. The acetabular cup prosthesis of Claim 1, wherein the polished surface is a polished mirror surface.

-24-

14. The acetabular cup prosthesis of Claim 11 or 13, further comprising grid means for inspecting the polished inner surface for defects.

15 15. The acetabular cup prosthesis of Claim 14, wherein the grid means is a grid comprised of a plurality of concentric rings.

16. The acetabular prosthesis of Claim 1 or 11 wherein the polymer liner is polyethylene.

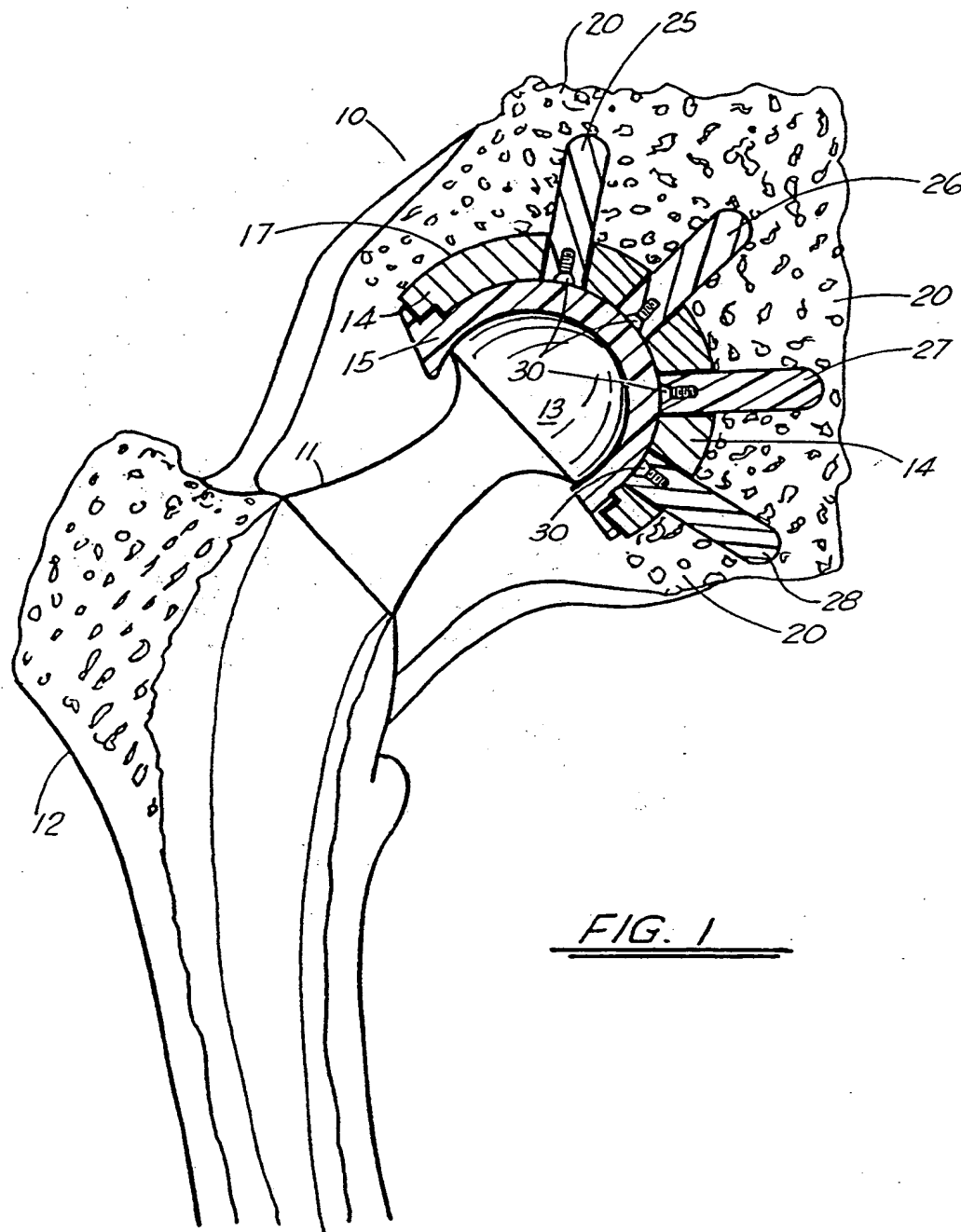
10 17. The acetabular prosthesis of Claim 14 wherein the mirror surface defines a lens to view the grid means.

18. The acetabular cup prosthesis of Claim 1 or 11 wherein the polished inner surface has a roughness of less than four (4) micro inches.

15 19. The acetabular cup prosthesis of Claim 1 or 11 wherein the polished inner surface has a roughness of between one (1) and four (4) micro inches.

20 20. The acetabular cup prosthesis of Claim 1, further comprising grid means for inspecting the polished inner surface for defects.

1/12



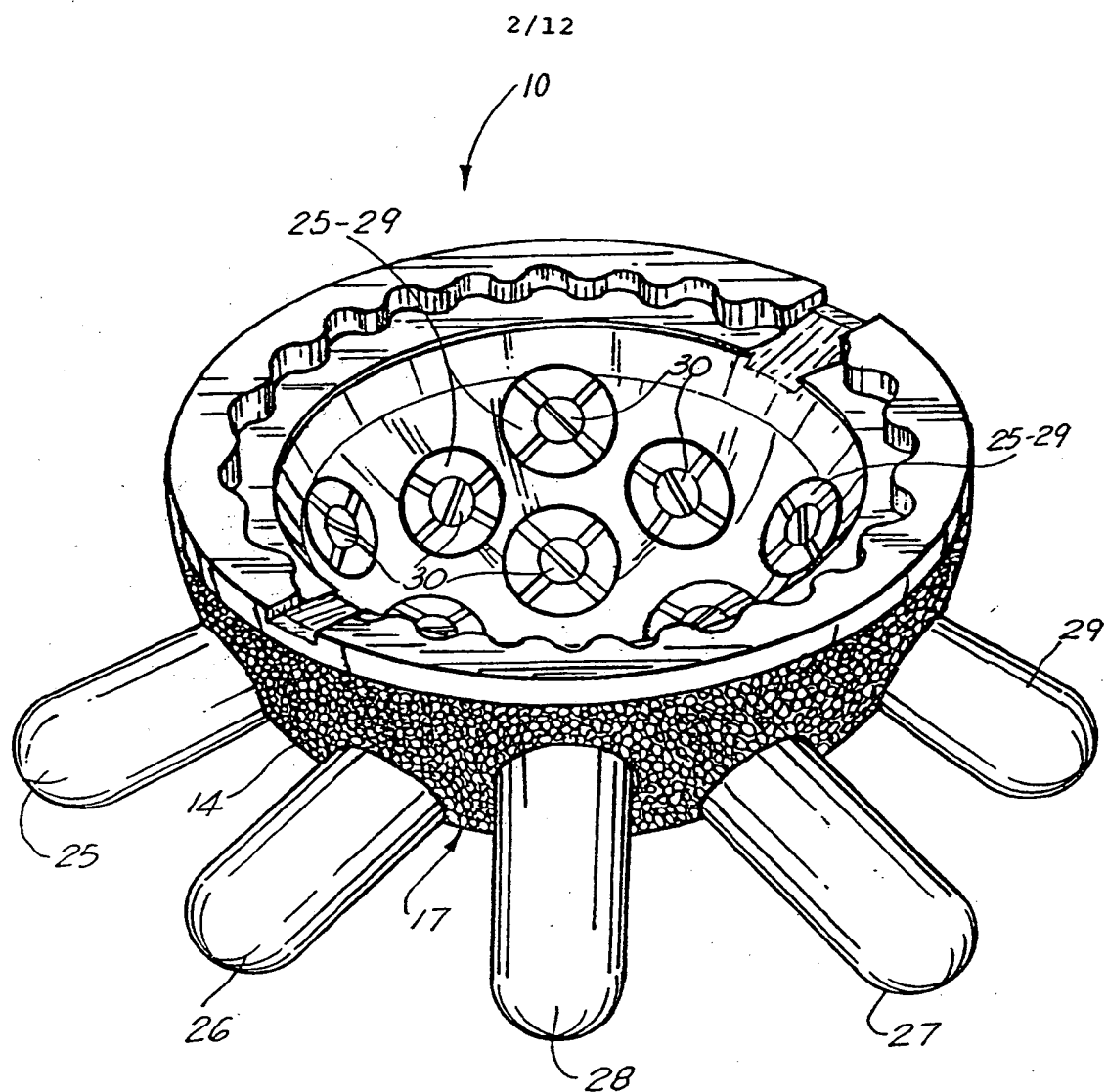


FIG. 2

3/12

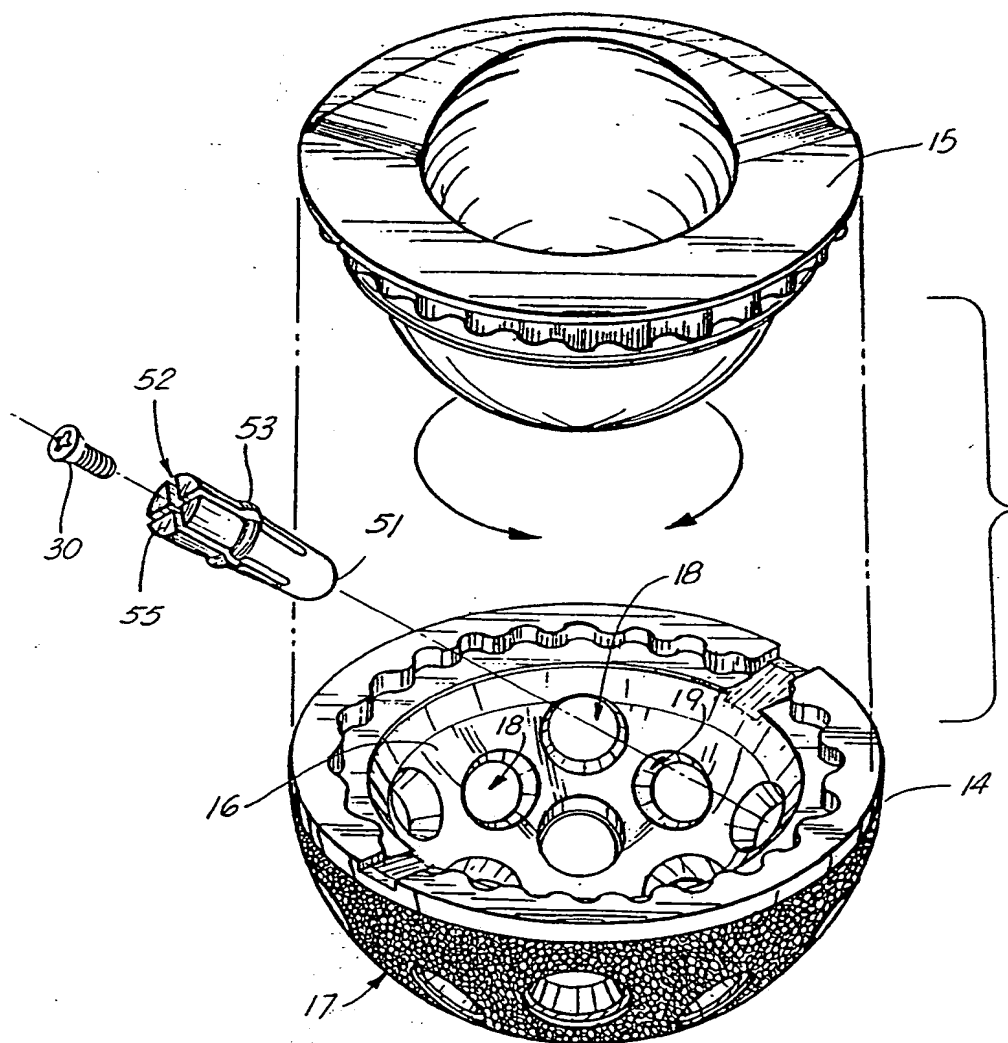


FIG. 3

4/12

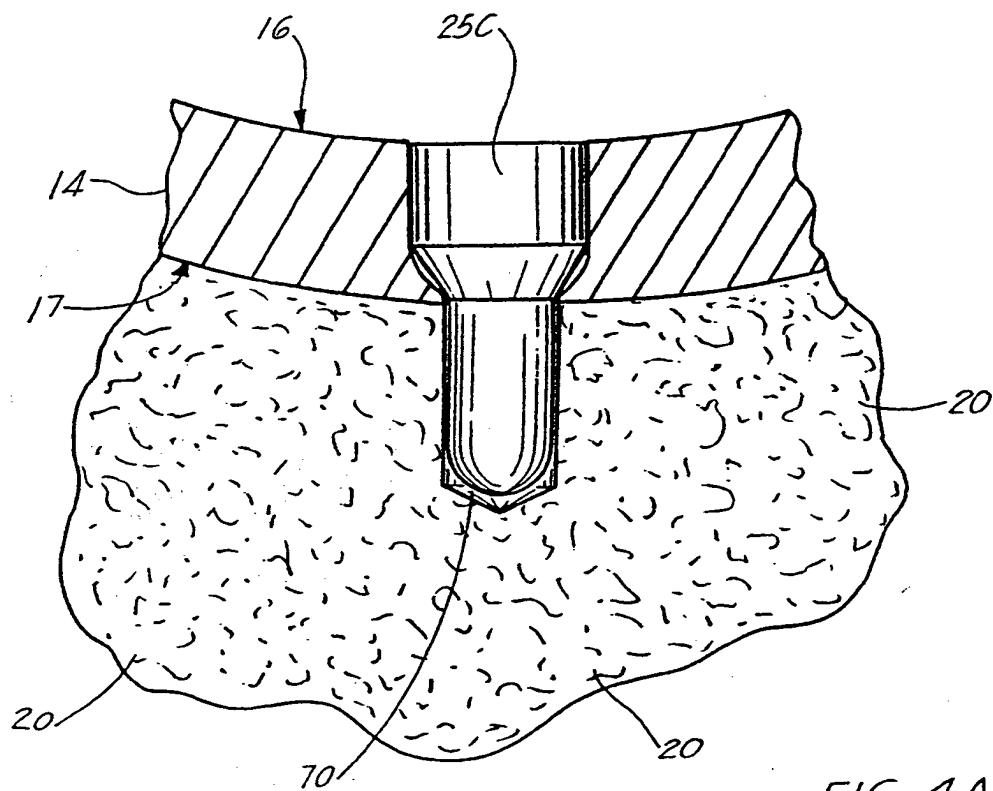


FIG. 4A

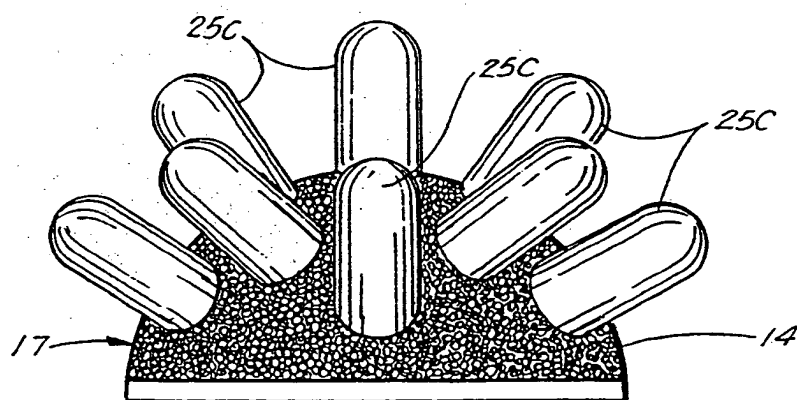


FIG. 4

5/12

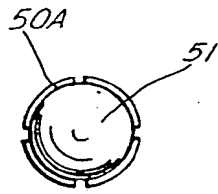


FIG. 5A

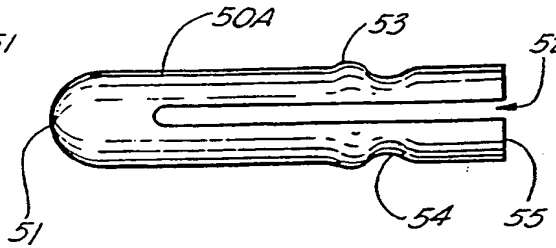


FIG. 5B

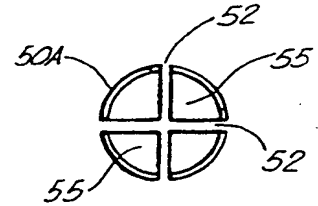


FIG. 5C

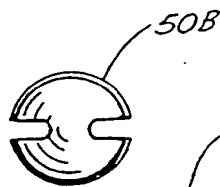


FIG. 6A

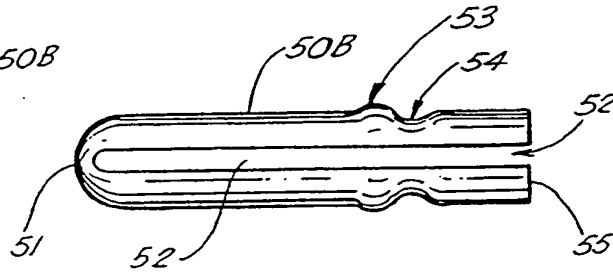


FIG. 6B

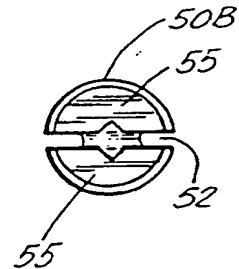


FIG. 6C

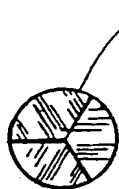


FIG. 7A

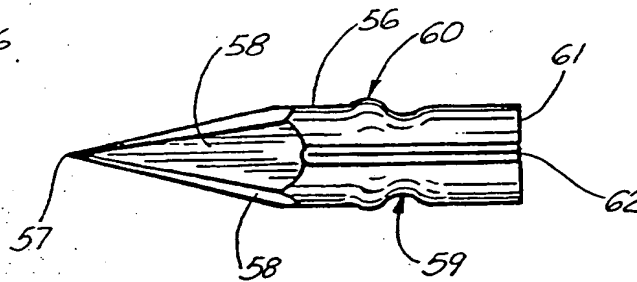


FIG. 7B

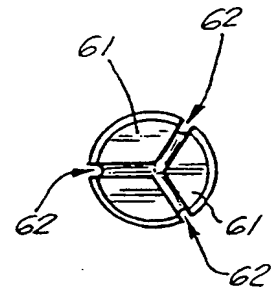


FIG. 7C

6/12

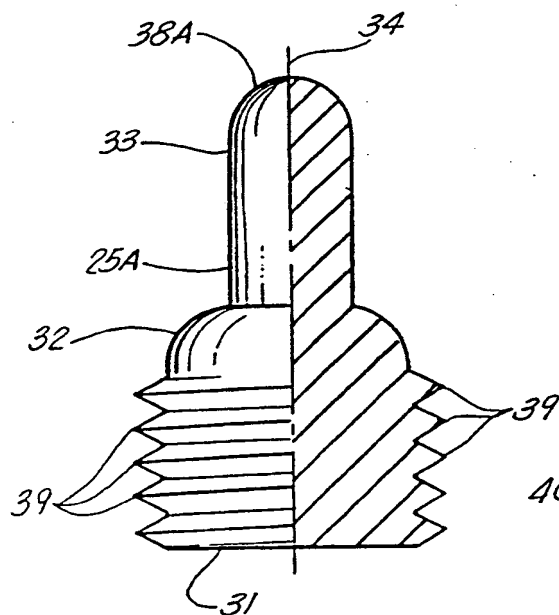


FIG. 8

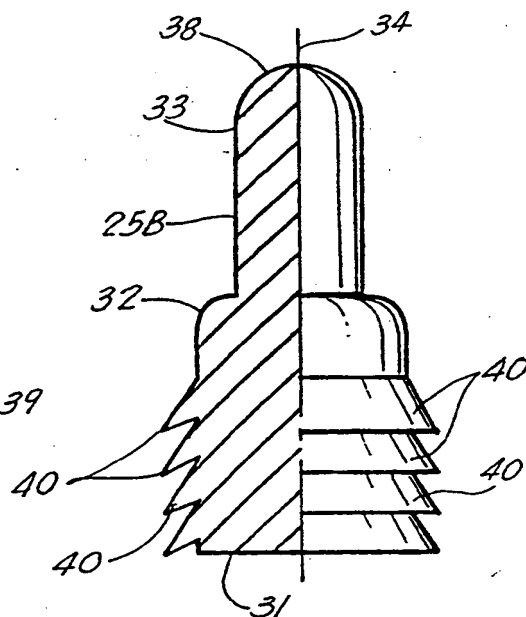


FIG. 9

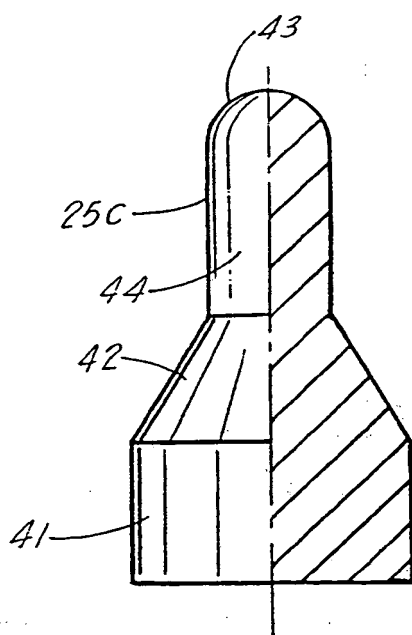


FIG. 10

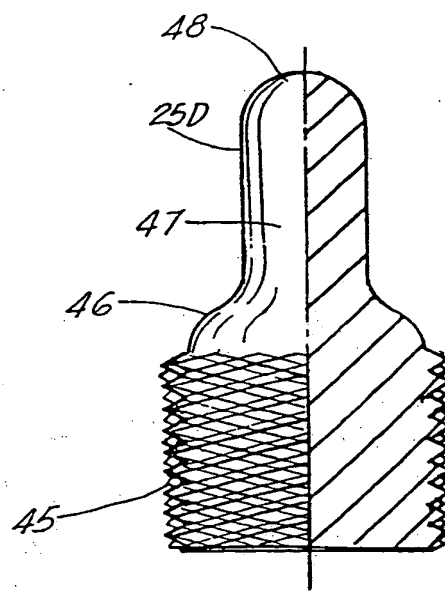


FIG. 11



7/12

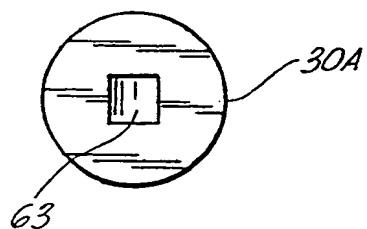


FIG. 12A

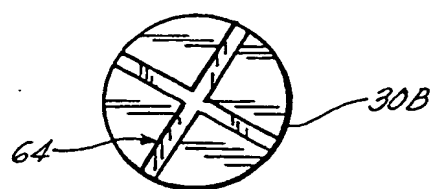


FIG. 12B

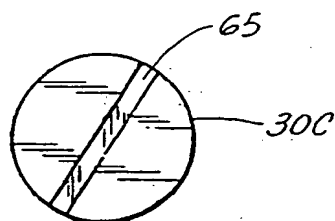


FIG. 12C

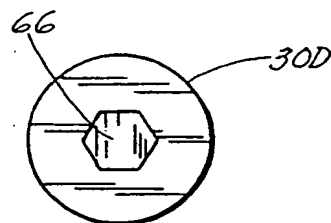


FIG. 12D

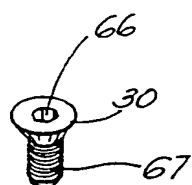


FIG. 13

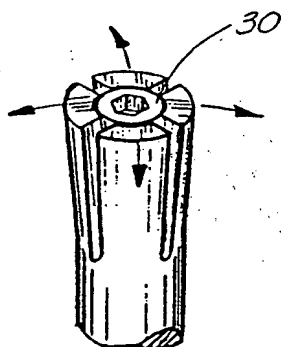


FIG. 14

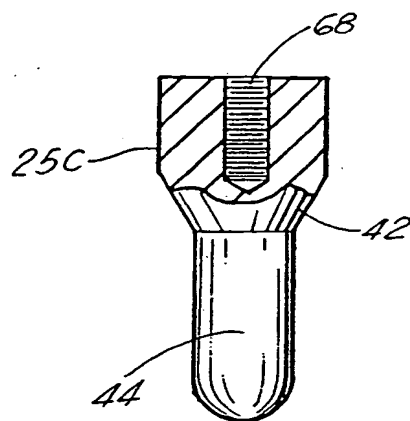


FIG. 15

8/12

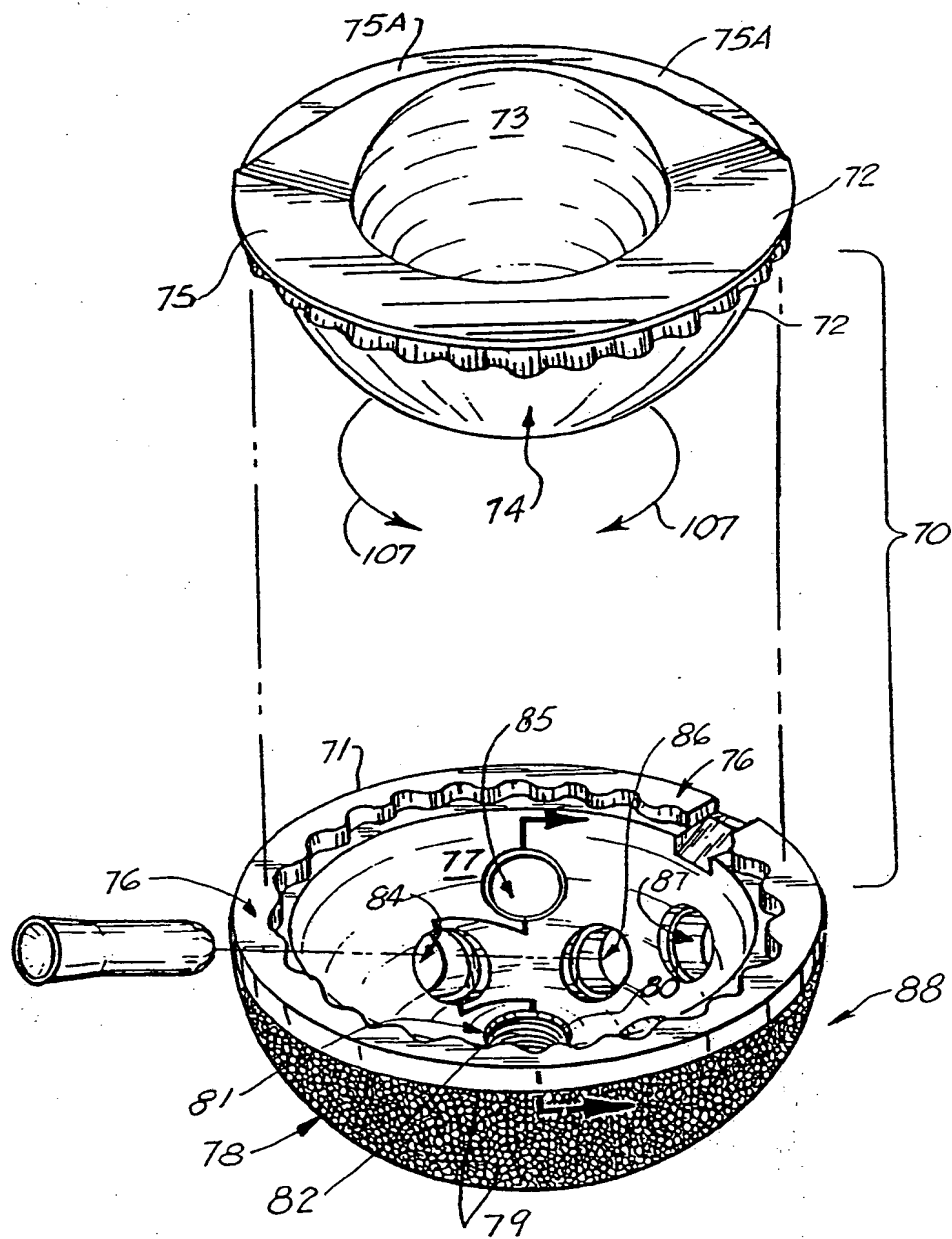


FIG. 16

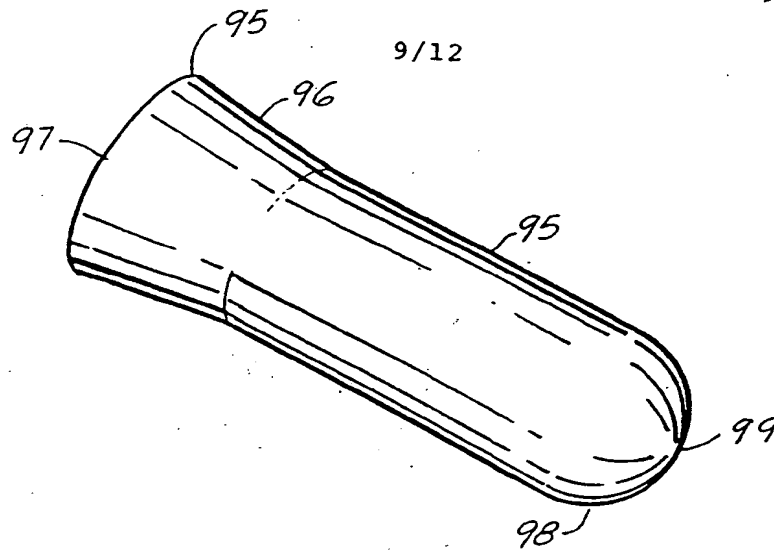


FIG. 17

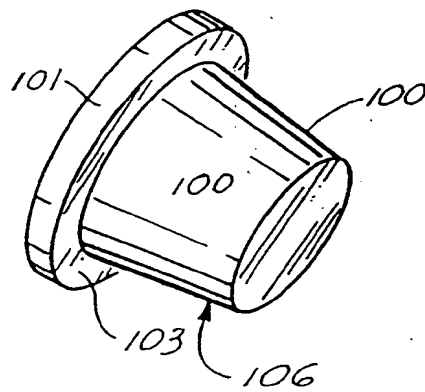


FIG. 18

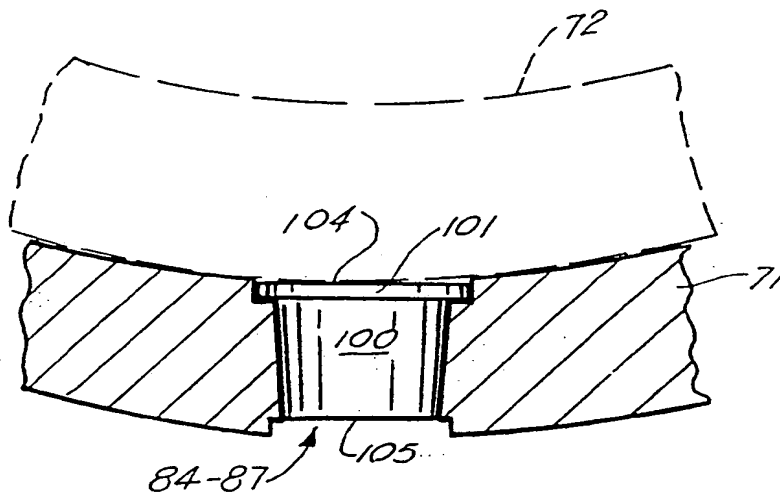
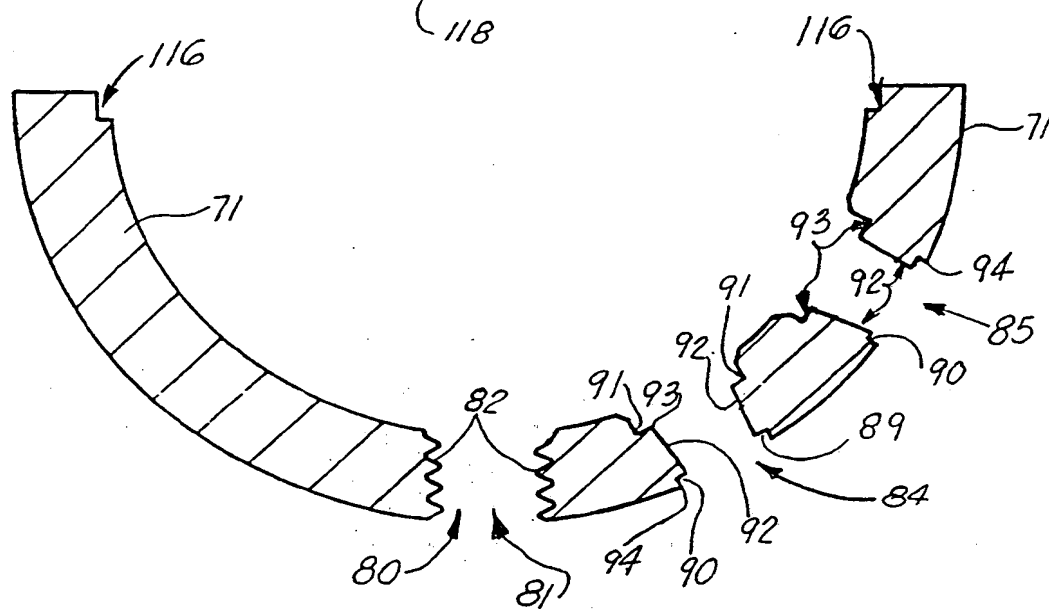
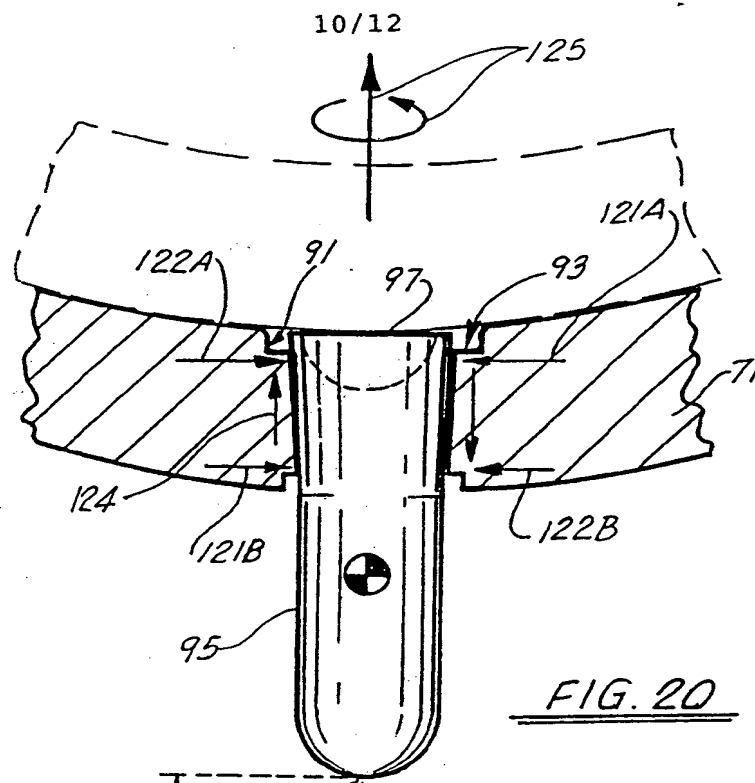
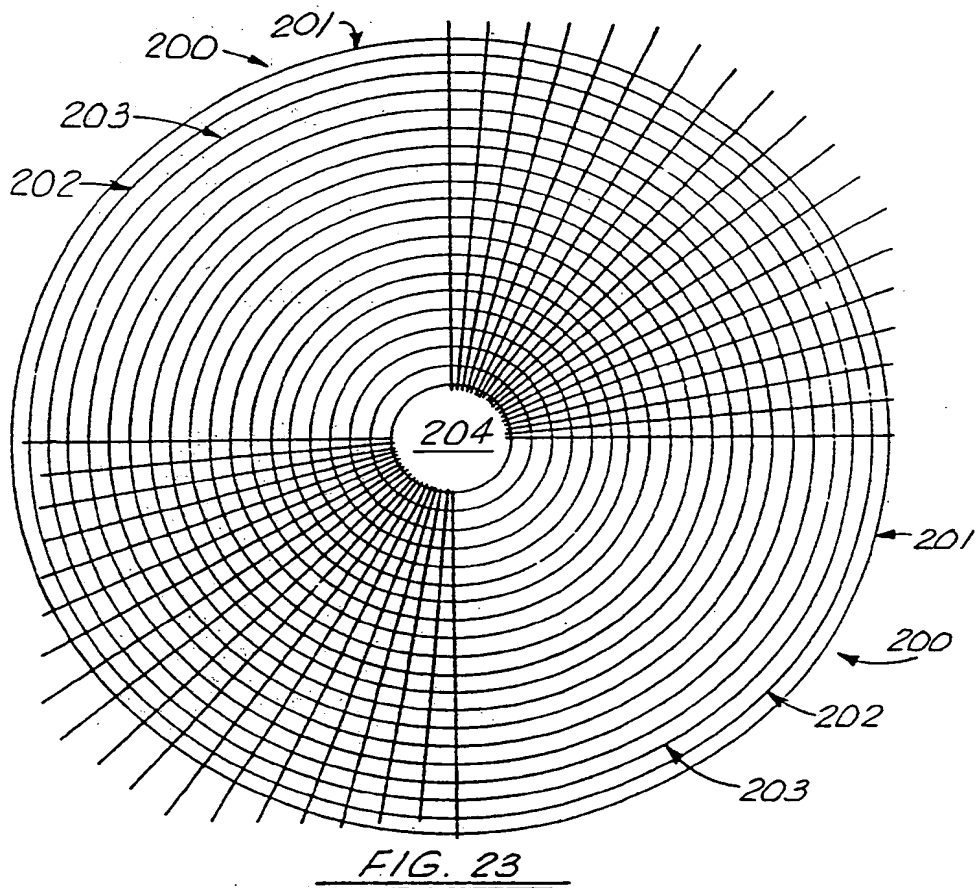
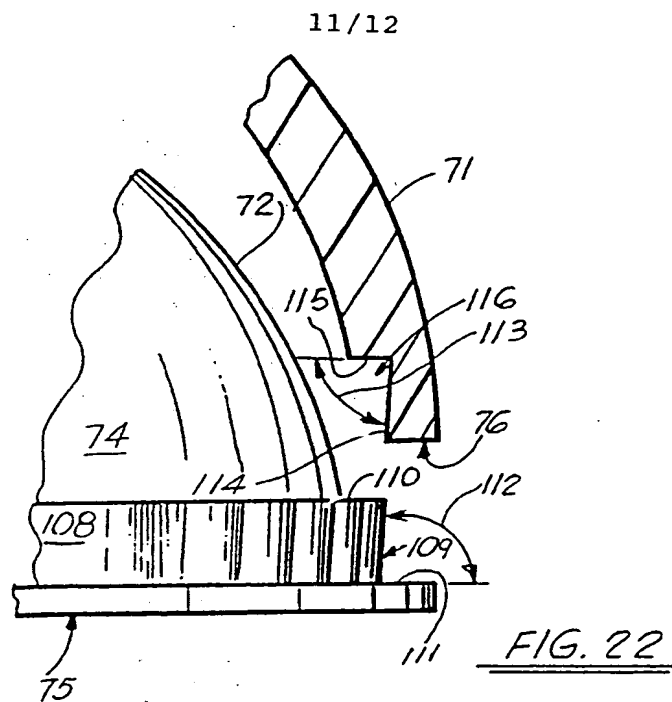


FIG. 19





12/12

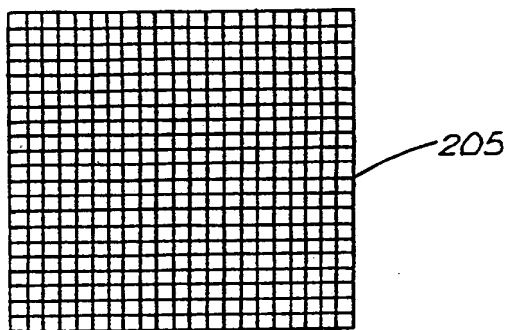


FIG. 24

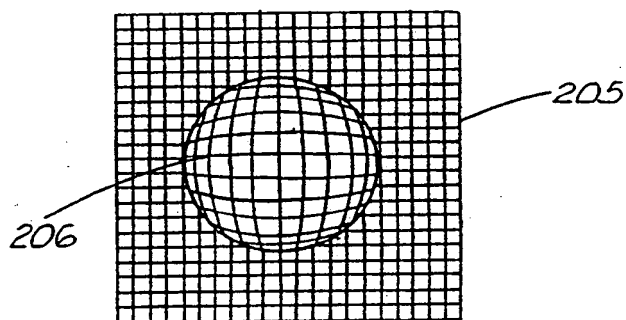


FIG. 25

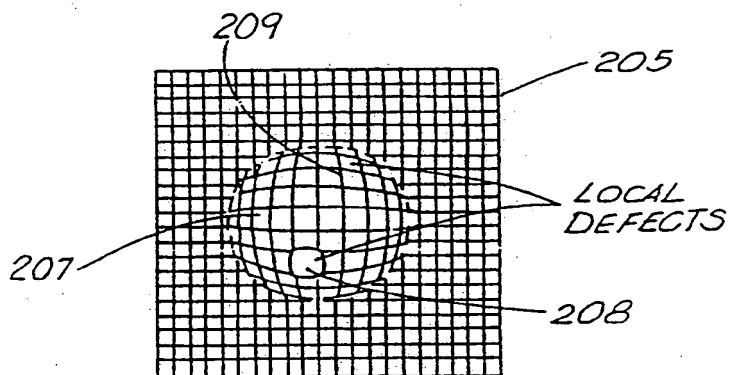


FIG. 26

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US93/08295

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61F 2/32

US CL :623/22

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/16, 18-20, 22, 23, 66

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,770,661 (Oh) 13 September 1988, see entire document.	1-20
A	US, A, 4,676,798(NOILES) 30 June 1987. See entire document.	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be part of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G*	document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means		
*P* document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 12 November 1993	Date of mailing of the international search report 12 JAN 1994
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer FOR ISABELLA, DAVID
Facsimile No. NOT APPLICABLE	Telephone No. (703) 308-3060

Form PCT/ISA/210 (second sheet)(July 1992)\*

**THIS PAGE BLANK (USPTO)**



**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☐ BLACK BORDERS

☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

☐ FADED TEXT OR DRAWING

☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING

☐ SKEWED/SLANTED IMAGES

☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS

☒ GRAY SCALE DOCUMENTS

☒ LINES OR MARKS ON ORIGINAL DOCUMENT

☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**

**THIS PAGE BLANK (USPTO)**